



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: S. Krishnaswamy, et al.

Serial No.: 09/363,728

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For: ANALYTE TEST INSTRUMENT SYSTEM
INCLUDING DATA MANAGEMENT SYSTEM

Examiner: Le, Uyen Chau N

Case No.: 6401.US.O1

Group Art Unit: 2876

Date: May 15, 2003

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BRIEF ON APPEAL

Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

This brief is in furtherance of the Notice of Appeal filed in this application on January 17, 2003.

The fees required under 1.17(f) and any required petition for extension of time for filing this brief (two months) and fees therefor are dealt with in the accompanying TRANSMITTAL OF BRIEF ON APPEAL. This brief is being submitted in triplicate. This brief contains these items under the following headings and in the order set forth below:

I. Real Party in Interest

II. Related Appeals and Interferences

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- III. Status of Claims
- IV. Status of Amendments
- V. Summary of the Invention
- VI. Issues
- VII. Grouping of Claims
- VIII. Argument
 - Rejection Under 35 U. S. C. § 103
 - Reason for Grouping of Claims
- IX. Appendix of Claims Involved in the Appeal

I. REAL PARTY IN INTEREST

The real party in interest is Abbott Laboratories, Abbott Park, Illinois.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-4 were filed in the original application. Claims 5, 6, and 7 were added in an AMENDMENT AND RESPONSE mailed May 21, 2001. Claim 7 was cancelled in an AMENDMENT AND RESPONSE mailed January 28, 2002. Claims 1-6 remain pending in the application. No claims are allowed. Claims 1-6 stand rejected. Claims 1-6 are on appeal.

IV. STATUS OF AMENDMENTS

No Amendment under 37 C.F.R. 1.116 was made after the Final Rejection.

V. SUMMARY OF INVENTION

This invention is directed to a hand-held analyte test instrument (10, 20). Referring to FIGS. 3A, 3B, 3C, and 4, the instrument (20) includes a user interface (24), a display (26), and a barcode reader (30) disposed in a housing (22). The user interface (24) includes a numeric keypad and function buttons to activate/deactivate power, select test or menu modes, edit entries,

terminate entries, and activate the bar code reader (30) as a substitute for manual numeric entry. The display (26) displays data relating to the analyte. The barcode reader (30) scans a barcode associated with a test strip (40) for receiving an analyte. The housing (22) also includes a port (36) for receiving the test strip (40).

Electronic circuitry (not shown) in electrical communication with the port (36) is used for processing a signal relating to the analyte received from the test strip (40) and generating data relating to the analyte. The instrument (20) also has a connector (38) in electrical communication with the circuitry and connectable with mating contacts in a docking station (70, FIGS. 11A, 11B) for data transfer, for recharging batteries from an external power source, and for communication with a printer. The circuitry automatically uploads data relating to the analyte to the host computer (14) when the connector (38) is linked to the host computer (14) (see FIG. 2, FIG. 14).

Referring to FIGS. 7A, 7B, 8A, 8B, 9A, 9B, the instrument (20) also includes a battery compartment (52) and a rechargeable battery pack (50). The battery compartment (52) includes a pair of electrical contacts (see FIG. 7B) for providing power from batteries (54, 56) to the circuitry, and a pair of recharging contacts (68). The rechargeable battery pack (50) is disposed in the battery compartment (52) and includes rechargeable batteries (54, 56) disposed in a battery holder (58), and bus bar contacts (64, 66) disposed in the battery holder (58). (One of the bus bar contacts 66 is erroneously identified as 64.) The bus bar contacts (64, 66) are in electrical communication with the pair of recharging contacts (68) for recharging the batteries (54, 56) when the instrument (20) is connected to the power source.

This invention also includes a docking station (12, 70, 84) for receiving the hand-held analyte test instrument (10, 20, 86). Referring to FIGS. 11A, 11B, 12, the docking station (70, 84) includes a connector (76), a switch (88), a first data port (80), a second data port (82), and a control mechanism (not shown). The connector (76) is electrically connectable to the instrument (20) for receiving data relating to the analyte. The switch (88) is in electrical communication with the connector (76). The first data port (80) and the

second data port (82) are in electrical communication with the switch (88). The first data port 80 is electrically connectable to a computer (14), and the second data port (82) is electrically connectable to a peripheral device (printer, FIG. 12). The control mechanism controls the switch (88) to selectively pass the data relating to the analyte to the computer (14) via the first data port (80) or to the peripheral device (printer, FIG. 12) via the second data port (82).

The invention provides a method of managing data for a plurality of analyte test instruments connected to a data communication network (see FIG. 14). The method includes the steps of detecting via a host computer the connection of each instrument to the network and uploading the data received from each instrument to the host computer. The method also includes the steps of processing the uploaded data on the host computer for operator review and downloading configuration data from the host computer to each instrument. The downloaded data includes setup and control data that can be specific to each instrument.

VI. ISSUES

1. Is claim 1 unpatentable under 35 U.S.C. § 102 (b) as being anticipated by Böcker et al. (U.S. Patent No. 5,507,288) in view of Cheung et al. (U.S. Patent No. 5,074,977)?
2. Is claim 3 unpatentable under 35 U.S.C. § 103 (a) as being obvious over Davis (U.S. Patent No. 5,502,943) in view of Koenck et al. (U.S. Patent No. 5,324,925) and Davis et al. (U.S. Patent No. 5,828,966)?
3. Is claim 4 unpatentable under 35 U.S.C. § 103 (a) as being obvious over Brown (U.S. Patent No. 5,307,263) in view of Cheung et al.?

4. Are claims 2 and 5-6 unpatentable under 35 U.S.C. § 103 (a) as being obvious over Böcker et al. (U.S. Patent No. 5,507,288) in view of Cargin Jr. et al. (U.S. Patent No. 5,602,456)?

VII. GROUPING OF CLAIMS

Claims 1-3, 5, and 6 stand or fall together. Claim 4 is separate from claims 1-3, 5, and 6.

VIII. ARGUMENT

Rejections Under 35 U.S.C. § 103

Issue 1

Böcker et al., U. S. Patent No. 5,507,288 (hereinafter "Böcker et al."), discloses an integrated analysis-element/sensor system comprising a sensor unit borne on the body of a patient and a central unit linked with the sensor unit by wireless data transmission. The central unit comprises the typical features of an evaluation instrument commonly used in element-analysis systems. It serves to evaluate an analysis-element in the form of a glucose test strip with a base layer and a test zone. The analysis-element is inserted into a test duct located beneath a flap of the central unit. A keypad is provided to operate the central unit. A display serves to display analytical data. An evaluation curve may be permanently stored in the central unit. Preferably, a separate, batch-specific evaluation curve is used for each new manufactured batch of analysis-elements and is transmitted to the central unit by means of a suitable data medium in machine-readable form. For that purpose, the central unit comprises a data reader, e.g., a barcode reader, to read a barcode affixed to the analysis-element itself or to an additional code

carrier. The barcode is included in each pack of analysis-elements and contains the batch-specific evaluation curve.

Cheung et al., U. S. Patent No. 5,074,977 (hereinafter "Cheung et al."), discloses a keypad and display to allow operator inputs and information outputs to be effected.

Although the examiner stated that claim 1 is anticipated (35 U. S. C. § 102 (b)) by Böcker et al. in view of Cheung et al., the Examiner further states that it would have been obvious to incorporate the conventional keypad as taught by Cheung et al. into the teachings of Böcker et al. in order to provide the user with a more flexibility in selecting which test to perform and in inputting the necessary data. Appellants will address this rejection as if it were based on 35 U. S. C. § 103.

Böcker et al. does not disclose or suggest a numeric keypad. Cheung et al. does not disclose or suggest a barcode reader. Thus, Böcker does not suggest the data entry mode employed by Cheung et al., and Cheung et al. does not suggest the data entry mode employed by Böcker et al. It follows then, that neither reference suggests the combination of a barcode reader and a numeric keypad. The suggestion that a certain modification be made in the basic reference must come from the other reference (the teaching reference), and not from applicant. Because Böcker et al. and Cheung et al. never recognized appellants' problem, neither of these references could have suggested its solution. Böcker et al. and Cheung et al. are improperly combined because there is no suggestion in either of them that they can be combined to produce appellants' result. Absence of a suggestion in Böcker et al. and Cheung et al. that the features of one should be combined with the features of the other to achieve the results of which neither reference alone is capable requires a conclusion that the rejection on the combination of the references is improper. It is not enough for a valid rejection to view the prior art in retrospect once an applicant's disclosure is known. The art applied should be viewed by itself to see if it fairly disclosed doing what appellants have done. If the art did not do so, the references have most likely been improperly combined. In order to negate invention, it is necessary to find in the prior art not merely a device which might be modified to make this

construction, but somewhere a suggestion not only that the modification ought to be made but how to make it.

Accordingly, because there is no suggestion in either of the references cited by the Examiner to provide a hand-held analyte test instrument having two different modes of data entry, it is submitted that the combination of Böcker et al. and Cheung et al. fails to render claim 1 obvious to one of ordinary skill in the art. It has been assumed that anticipation is not a valid ground of rejection when two references are combined to bring about a rejection.

Issue 2

Davis, U. S. Patent No. 5,502,943 (hereinafter "Davis '943"), discloses a dock apparatus for receiving portable, hand-held data retrieval devices to allow recharging internal batteries and data communication with centralized computer systems. A frame having electrical contact elements at its inner end receives the hand-held device, which at its lower end is provided with electrical contact pads, which engage the contact elements of the receiving frame when the hand-held device is fully inserted in the frame. Detents within the frame engage mating indentations in the hand-held device. The dock frames may be ganged in plural arrangements.

Koenck et al., U. S. Patent No. 5,324,925 (hereinafter "Koenck et al."), discloses a hand-held portable terminal, comprising:

- (a) a housing having a front section and a rear section, a forward end and a rearward end, the front section being hinged to the rear section;
- (b) key means being disposed within the housing for entering information into the terminal;
- (c) display means disposed within the housing for displaying information;
- (d) a low power, frequency hopping, transceiver means disposed at least partially within the housing for receiving and transmitting information by the terminal;

- (e) scanning means disposed within the housing for optically reading information stored in coded information sets;
- (f) battery means disposed within the housing for providing electrical power thereto; and
- (g) means, disposed within the housing, for processing information input and output the terminal.

Davis et al., U. S. Patent No. 5,828,966, (hereinafter "Davis et al. '966"), discloses a charging cradle adapted to hold a telephone in a nested relation while recharging the batteries located within the telephone. Safety features prevent overcharging.

Koenck et al. discloses a docking station (34) having a plurality of docking ports (36). However, Koenck et al. does not disclose or suggest a docking station having a first data port being electrically connectable to a computer and a second data port being electrically connectable to a peripheral device, the docking station being configured to pass data between an analyte test instrument and the first data port when the docking station is in a default condition. While Davis '943 does generally disclose a dock apparatus to allow recharging of internal batteries, Davis '943 does not remedy the deficiency of Koenck et al. mentioned previously. While Davis et al. '966 does generally disclose safety features to prevent overcharging, Davis et al. '966 does not remedy the deficiency of Koenck et al. mentioned previously. Thus, the combination of Davis '943, Koenck et al., and Davis et al. '966 fails to disclose or suggest a docking station that includes (1) a first data port being electrically connectable to a computer, (2) a second data port being electrically connectable to a peripheral device, and (3) a docking station being configured to pass data between the analyte test instrument and the first data port when the docking station is in a default condition. For this reason, it is submitted that the combination of Davis '943, Koenck et al., and Davis et al. '966 does not render claim 3 obvious to one of ordinary skill in the art.

Issue 3

Brown, U. S. Patent No. 5,307,263 (hereinafter "Brown"), discloses a modular self-care health monitoring system which employs a small handheld microprocessor-based unit such as a compact video game system of the type that includes a display screen, switches for controlling device operation and a program cartridge that is inserted into the handheld unit to adapt it for operation with a microprocessor-based healthcare data management unit and a glucose monitor or another type of health monitor. A modem, included in the microprocessor-based healthcare data management unit, allows data such as blood glucose level to be transmitted to a clearinghouse, which transmits reports to a remotely located healthcare professional via facsimile transmission.

According to Cheung et al., the sensor element 16 is inserted into the console 12, much like any test strip is inserted in to a glucose monitor. Cheung et al. does not disclose or suggest the use of a console 12 in combination with a docking station. Cheung et al. is primarily concerned with the characteristics of the detector -- the insulated-gate, field-effect transistor. Brown does disclose a health monitoring system. In Brown, the glucose monitor can be plugged into the data management unit 10. Brown does not disclose or suggest that the glucose monitor can be inserted into the hand held unit 12. There is no suggestion in Cheung et al. to modify the system described in Brown to allow insertion of a glucose monitor into the hand held unit 12. There is no suggestion in Brown to arrange a network having a plurality of consoles plugged into a plurality of docking stations. Thus, no matter how Cheung et al. is combined with Brown, the ultimate result will not be a system that can perform the method recited in claim 4 of this application, which system requires (a) a plurality of analyte test instruments connected to a data communication network and (b) each of the analyte test instruments of the plurality of analyte test instruments includes a test strip port, which accepts test strips for determining the level of analyte in a sample taken from a patient. For this reason, it is submitted that the combination of Brown and

Cheung et al. does not render claim 4 obvious to one of ordinary skill in the art.

Issue 4

Cargin Jr. et al., U. S. Patent No. 5,602,456 (hereinafter "Cargin Jr. et al."), discloses a battery pack system for providing rechargeable battery power for a portable data collection terminal and for enabling recharging while received in power supplying relation to such a terminal.

Böcker discloses a barcode reader. Cargin Jr. et al. discloses a user interface capable of allowing an operator to enter data. Neither Böcker nor Cargin Jr. et al. discloses or suggests an analyte test instrument having both a user interface capable of allowing an operator to enter data and a barcode reader disposed in the housing for scanning a barcode associated with a test strip configured to receive an analyte. Moreover, neither Böcker nor Cargin Jr. et al. contains a suggestion to combine (1) a barcode reader disposed in the housing for scanning a barcode associated with a test strip configured to receive an analyte and (2) a user interface capable of allowing an operator to enter data in an analyte test instrument. The suggestion that a certain modification be made in the basic reference ("Böcker") must come from the other ("teaching") reference ("Cargin Jr. et al."), and not from applicant. Because neither Böcker nor Cargin Jr. et al. recognized appellants' problem, neither of these references could have suggested its solution. Böcker and Cargin Jr. et al. are improperly combined because there is no suggestion in either of them that they can or should be combined to produce appellants' result. Absence of a suggestion in Böcker and Cargin Jr. et al. that the features of one should be combined with the features of the other to achieve the results of which neither reference alone is capable requires a conclusion that the rejection on the combination of the references is improper. As stated previously, it is not enough for a valid rejection to view the prior art in retrospect once an applicant's disclosure is known. The art applied should be viewed by itself to see if it fairly disclosed doing what appellants have done. If the art did not do so, the references have been improperly combined. In order

to negate invention it is necessary to find in the prior art not merely a device which might be modified to make this construction, but somewhere a suggestion not only that the modification ought to be made but how to make it. Accordingly, the combination of Böcker and Cargin Jr. et al. is improper and cannot render claims 2 and 5-6 obvious to one of ordinary skill in the art.

REASONS FOR SEPARATING CLAIMS 1-3, 5, AND 6 FROM CLAIM 4

Claims 1, 2, 5, and 6 relate to a specific type of hand-held instrument for determining the concentration of an analyte in a biological sample. Claim 3 relates to a specific type of docking station for the specific type of hand-held instrument. Accordingly, it is logical to group claims 1, 2, 3, 5, and 6.

Claim 4 relates to a method of managing data for a plurality of analyte test instruments connected to a data communications network. The specific type of hand-held instrument for determining the concentration of an analyte in a biological sample and the specific type of docking station for the hand-held instrument need not be used in the method described in claim 4. Accordingly, it is submitted that a decision relating to the patentability of claim 4 should not affect the decision relating to patentability of claims 1, 2, 3, 5, and 6.

CONCLUSION

In view of the foregoing, it is submitted that claims 1-6 are in condition for allowance, and it is requested that the Final Rejection be reversed.

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Respectfully submitted
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A handwritten signature in cursive script, reading "David L. Weinstein".

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APPENDIX OF CLAIMS

The text of the claims on appeal is:

1. (Twice amended) A hand-held analyte test instrument comprising:

- a housing;
- a barcode reader disposed in the housing for scanning a barcode associated with a test strip configured to receive an analyte;
- a user interface capable of activating said barcode reader, said user interface further comprising a numeric keypad and at least one function button, said at least one function button capable of carrying out at least one of the functions of activating/deactivating power, selecting test or menu modes, editing entries, terminating entries, and activating a barcode reader as a substitute for numerical entry;
- a port disposed in the housing for receiving the test strip;
- electronic circuitry in electrical communication with the port for processing an analyte signal received from the test strip and generating analyte data therefrom;
- a display in electrical communication with the circuitry for displaying certain analyte data; and
- a connector in electrical communication with the circuitry and electrically connectable to a host computer via a data communications network, wherein the circuitry automatically uploads the analyte data to the host computer upon connection thereto.

2. (Twice amended) A hand-held analyte test instrument comprising:

- a housing;
- a port disposed in the housing for receiving a test strip configured to receive an analyte;
- a barcode reader disposed in the housing for scanning a barcode associated with a test strip configured to receive an analyte;

a user interface capable of allowing an operator to enter data, said user interface comprising a numeric keypad and at least one function button, said at least one function button capable of carrying out at least one of the functions of activating/deactivating power, selecting test or menu modes, editing entries, terminating entries, and activating a barcode reader as a substitute for numerical entry;

electronic circuitry in electrical communication with the port for processing an analyte signal received from the test strip and generating analyte data therefrom;

a display in electrical communication with the circuitry for displaying certain analyte data;

a connector in electrical communication with the circuitry and electrically connectable to a power source;

a battery compartment formed in the housing and comprising a pair of electrical contacts for providing power from a battery to the electronic circuitry and a pair of recharge contacts; and

a rechargeable battery pack disposed in the battery compartment and comprising (1) a rechargeable battery and (2) a battery holder in which the rechargeable battery is disposed, a bus bar disposed on the battery holder and in electrical communication with the pair of recharge contacts for recharging the battery when the instrument is connected to the power source.

3. (Twice amended) A docking station for receiving a hand-held analyte test instrument, the docking station comprising:

a connector electrically connectable to the instrument for receiving analyte data therefrom;

a switch in electrical communication with the connector;

a first data port in electrical communication with the switch and being electrically connectable to a computer;

a second data port in electrical communication with the switch and being electrically connectable to a peripheral device; and

a control mechanism for controlling the switch to selectively pass the analyte data to the computer via the first data port or to the peripheral device via the second data port; said docking station being configured to pass data

between said analyte test instrument and said first data port when said docking station is in a default condition, and
circuitry to prevent overcharging.

4. (Twice amended) A method of managing data for a plurality of analyte test instruments connected to a data communication network comprising the steps of:

detecting via a host computer the connection of each analyte test instrument of said plurality of analyte test instruments to the data communication network, each of said analyte test instruments of said plurality of analyte test instruments including a test strip port, which accepts test strips for determining the level of analyte in a sample taken from a patient;

uploading data received from each analyte test instrument of said plurality of analyte test instruments to the host computer; and

processing the uploaded data on the host computer for operator review; and downloading configuration data from the host computer to each analyte test instrument of said plurality of analyte test instruments, the downloaded data comprising instrument-specific setup and control data.

5. The instrument of claim 1, wherein said user interface is further capable of allowing an operator to enter data.

6. The instrument of claim 2, wherein said barcode reader is capable of being activated by said user interface.